

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT		ATTORI	NEY DOCKET NO.
		i de la companya de l			
	100 Sept. 1	J [EXAMINE	R
en tibble per en la fest en frage			· 1.00		
		 -	ARTUN	17 0	ADED AU MADED
· · · · · · · · · · · · · · · · · · ·		· ·	ART UN		APER NUMBER
		Ĺ			6
			ATE MAILEC): 02	1/25/82
		in charge of your application.			7- 780
COM	MISSIONER OF PAI	ENTS AND TRADEMARKS			
)) ,		
This application ha	s been examined.	Responsive to communication filed on 12/2	182	[]	nis action is made fin
		this action is set to expire month(s),			
Failure to respond with	in the period for resp	onse will cause the application to become abandone	day d. 35 U.S	ys from the da S.C. 133	te of this letter.
		IT(S) ARE PART OF THIS ACTION:			
1. Notice of Re	eferences Cited by Ex	aminer, PTO-892 2. Notice of Infor	mal Patent D	rawing, PTO-9	948
3. Notice of R	eferences Cited by Ap			opplication, F	orm PTO-152
Part II SUMMARY	OF ACTION	5.		,	
1. Claims	19			_ are pending	in the application.
Of the above					vn from consideratio
		*			
4. Dtáims	19	-		_ are rejected.	
5. Claims				_ are objected	to.
6. Claims			are subject to	o restriction o	election requiremen
					•
			_	approved.	∏disapproved.
			•		
been re		aim for priority under 35 U.S.C. 119. The certified connection of the certified in parent application, se			
		filed on	rrial no		,
					
10. Since this app cordance with	lication appears to be the practice under E	in condition for allowance except for formal matter x parte Quayle, 1935 C.D. 11; 453 O.G. 213.	s, prosecution	n as to the me	rits is closed in ac-
11. Other					

PTOL-326 (rev. 7-79)

EXAMINER'S ACTION

Serial No. 230,578
Art Unit 125

The references presented by applicants should be cited on a notice of references cited by applicant, PT-1449 form.

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-19 are rejected under 35 U.S.C. 101 because there is insufficient evidence of record demonstrating the applicants' compound is effective for treating cancer in humans. The case histories in the references are incomplete as to form and substance in the omission of a protocol and complete pertinent date for evaluation of the results by one skilled in the art. The data of record is obviously no substitute for a showing of such utility in humous by proper evidence with statistically significant date, based on all tests unducted. In re Buting 163 U.S.P.Q. 689

Claims 1-19 are rejected as being based on an insufficient disclosure under 35 USC 112, first paragraph. The term "neoplastic disease" in claim 1 and 2; "pulmonary metastatic tumor" in claim 3;

Serial No. 230,578
Art Unit 125

"breast cancer" in claim 4 and 5; "lung cancer" in claims 6 and 7; "malignant melanoma" in claim 8 and 9; "colorectal cancer" in claim 10 and 11; "multiple myeloma" in claims 12 and 13; "head and neck cancer" in claim 14 and 15; "bladder cancer" in claims 16 and 17 and "gastric cancer" in claims 18 and 19 lack clear examplary support in the specification as filed. The limited number of examples set forth in the specification will obviously not support such broad terms.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

JDGoldberg:adj

A/C 703

557-2575

02/15/83

EROJE D. GOLDBERG

GROUP ART UNIT 125